UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

B

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,526	07/07/2005	Stephen Robert Bloom	AI 9250US	6041

23579 7590 02/23/2007

PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE, SUITE 1200
1201 PEACHTREE STREET
ATLANTA, GA 30361

EXAMINER	
KOSAR, ANDREW D	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,526	BLOOM ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-61* is/are pending in the application.

4a) Of the above claim(s) *38-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/8/05;3/20/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV, with GLP-1 as the second agent, in the reply filed on November 27, 2006 is acknowledged. The traversal is on the ground(s) that the methods all require the same step, administration of oxyntomodulin (OXM) with an additional agent. This has not been found persuasive for the following reasons. While Applicant has stated that, "***There is no difference in the method steps between the alleged groups of Groups II, III, IV, V and VI***" (emphasis in original, *Remarks*, page 3), Applicant has neither provided evidence nor stated clearly on the record that the methods are obvious variants of each other, as the restriction requirement clearly stated, "Should applicant traverse on the ground that the inventions or species are not patentably distinct, *applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case*. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention." (emphasis added; *Restriction requirement* of 10/26/06, paragraph spanning pages 5 and 6).

However, upon further consideration, the examiner has reconsidered the requirement, and has withdrawn the restriction between the methods (Groups II-VI).

With regards to the Applicant's interpretation that the products (Group I) would be rejoined and fully examined upon allowance of the method claims (*Remarks*, page 4), respectfully, Applicant has misinterpreted rejoinder practice. The rejoinder practice is such that

if the product is elected and found to be allowable, the method of using the allowable product will be rejoined and examined. In electing the method, the products are not subject to rejoinder.

The requirement is still deemed proper and is therefore made FINAL.

Claims 38-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 27, 2006. Claims 48-61 have been examined on the merits.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claims 48 is objected to because of the following informalities:

Claim 48 is objected to for not ending in a period. MPEP § 804.01(m) states that, "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995)."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 56-59 recites the broad recitation "at a dose of 0.1 nmoles per kg body weight of the subject or more... up to 3.2 nmoles per kg body weight," (claim 56), "in an amount of up to 3.0 nmoles per kg body weight," (claim 57), ""up to 12 nmoles per kg body weight," and "at a dose of up to 11 nmoles per kg body weight," (claim 59), and the claims also recite, "for example," and enumerate several 'examples' within the defined range, which is the narrower statement of the range/limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 48-50 and 52-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over KNUDSEN (WO 98/20895 A1) in view of DAKIN (C.L. Dakin et al. Am. J. Physiol. Endocrinol. Metab. (2002) 283, pages E1173-E1177; PTO-1449, 11/8/05)

The instant claims are drawn generally to weight control or treatment with oxyntomodulin (OXM) and an additional agent.

Knudsen teaches GLP-1, fragments and analogs in medicaments for suppression of appetite and induction of satiety (e.g. abstract). The fragments include oxyntomodulin (OXM) (e.g. claim 4, OXM is GLP-1 (1-37)). Knudsen further teaches methods of treating or preventing disorders associated with impaired appetite regulation or feeling of satiety, comprising administering any of the GLP-1 compounds (e.g. claim 18) and treating or preventing obesity with the compounds (claim 19). Knudsen teaches that the compounds may be administered parenterally (subcutaneous, im, ip, iv), as a powder or liquid for a nasal or pulmonary spray, transdermally, or as a composition for buccal, rectal or vaginal administration (page 8, lines 19-28), and provides various conditions for formulating the compositions (e.g. pages 8-10).

Dakin OXM causes a reduction in daily food intake, a significant reduction in body weight gain and a decrease in adipose tissue as well as an increase in energy expenditure. The art further recognizes that, "like GLP-1, chronic administration of OXM can reduce body weight gain and that this effect is not due solely to the reduction in daily food intake. There is a decrease in white adipose tissue and an increase in core temperature in OXM-treated animals that

is not seen in pair-fed animals, suggesting that, in addition to inhibiting food intake, OXM might also enhance energy expenditure." (E1177).

The difference between that which is instantly claimed and the teachings of the prior art, is that while the art teaches OXM and GLP-1 for treating weight related conditions, it does not teach them being coadministered in the treatment.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

Here, both OXM and GLP-1 (and GLP-1 fragments) are taught in the art to be used in reducing weight gain, e.g. obesity, and thus it is *prima facie* obvious to combine OXM and GLP-1, or a fragment of GLP-1, to make and use a third composition which is useful for reducing weight gain, e.g. obesity.

Furthermore, it is intrinsic that in administration of the composition to reduce weight gain, one is decreasing calorie intake, food intake and appetite, as well as increasing energy expenditure, as OXM is specifically taught in the art to provide those effects, thus resulting in reducing weight gain, promoting weight loss and reducing obesity. Additionally, one would logically conclude that if one were decreasing food intake, appetite and calorie intake, one is intrinsically controlling appetite, satiety and hunger, preventing weight gain and obesity, as well as alleviating a condition or disorder which can be alleviated by reducing nutrient availability and/or by increasing energy expenditure and improving lipid profile, maintaining a desired body weight, BMI and/or appearance and good health.

With regards to the route of administration, it would have been obvious to formulate the composition for any route of administration, as Knudsen teaches GLP-1, and it's fragments, including OXM, can be formulated and administered via any route of administration. One would have been motivated to formulate the composition for any route of administration, with a reasonable expectation for success in formulating and administering the composition via any route of administration, as Knudsen teaches the compounds can be formulated and administered in any manner.

With regards to the various doses of compound administered, It would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g.concentration/dose of OXM and/or GLP-1 administered), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05). One would have been motivated to have determined the optimal concentrations/doses of OXM and GLP-1 in order to determine the optimum or workable ranges for combining the two compounds, and one would have had a reasonable expectation for success in doing so, as it is considered routine experimentation to optimize the conditions, e.g. dosages administered.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 48-61 rejected under 35 U.S.C. 103(a) as being unpatentable over KNUDSEN in view of DAKIN as applied to claims 48-50 and 52-61 above, and further in view of BRYANT (WO 01/87335 A2).

The claims are further drawn to the method where the effect is due to a reduction of circulating ghrelin levels.

Bryant teaches ghrelin neutralizing agents (GNA) as a pharmaceutical (claim 14) and their use in treating obesity and related disorders (e.g. claims 2, 6, 7 and 16).

The difference between that which is instantly claimed and the teachings of the prior art, is that while the art teaches OXM, GLP-1 and GNA for treating weight related conditions, it does not teach them being coadministered in the treatment.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

Here, OXM, GLP-1 (and GLP-1 fragments) and GNA are taught in the art to be used in reducing weight gain, e.g. obesity, and thus it is *prima facie* obvious to combine OXM, GLP-1 (or a fragment of GLP-1) and GNA, to make and use a third composition which is useful for reducing weight gain, e.g. obesity.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 48-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/488,341 in view of KNUDSEN, DAKIN or BRYANT, *supra.*

The instant claims are generally drawn to treating weight disorders, e.g. obesity.

The teachings of Knudsen, Dakin and Bryant are presented *supra.*

10/488,341 claims a method for prevention or treatment of excess weight in a mammal comprising administering a composition comprising OXM, an analog, salt, conjugate or chemically modified version thereof (claim 1), where OXM is human OXM (claim 15).

The difference between that which is instantly claimed and the teachings of the prior art, is that while the art teaches OXM and GLP-1 for treating weight related conditions, it does not teach them being coadministered in the treatment.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art."

Here, OXM, GLP-1 (and GLP-1 fragments) and GNA are taught in the art to be used in reducing weight gain, e.g. obesity, and thus it is *prima facie* obvious to combine OXM, GLP-1 (or a fragment of GLP-1) and GNA, to make and use a third composition which is useful for reducing weight gain, e.g. obesity.

Furthermore, it is intrinsic that in administration of the composition to reduce weight gain, one is decreasing calorie intake, food intake and appetite, as well as increasing energy expenditure, as OXM is specifically taught in the art to provide those effects, thus resulting in reducing weight gain, promoting weight loss and reducing obesity. Additionally, one would logically conclude that if one were decreasing food intake, appetite and calorie intake, one is intrinsically controlling appetite, satiety and hunger, preventing weight gain and obesity, as well as alleviating a condition or disorder which can be alleviated by reducing nutrient availability and/or by increasing energy expenditure and improving lipid profile, maintaining a desired body weight, BMI and/or appearance and good health.

With regards to the route of administration, it would have been obvious to formulate the composition for any route of administration, as Knudsen teaches GLP-1, and it's fragments,

including OXM, can be formulated and administered via any route of administration. One would have been motivated to formulate the composition for any route of administration, with a reasonable expectation for success in formulating and administering the composition via any route of administration, as Knudsen teaches the compounds can be formulated and administered in any manner.

With regards to the various doses of compound administered, It would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g.concentration/dose of OXM and/or GLP-1 administered), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05). One would have been motivated to have determined the optimal concentrations/doses of OXM and GLP-1 in order to determine the optimum or workable ranges for combining the two compounds, and one would have had a reasonable expectation for success in doing so, as it is considered routine experimentation to optimize the conditions, e.g. dosages administered.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This is a provisional obviousness-type double patenting rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 5,912,227 teaches that PYY and PYY agonists increase nutrient uptake and cause weight gain, and PYY antagonists decrease nutrient uptake.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew D. Kosar 2/6/07

Andrew D. Kosar
Examiner
Art Unit 1654